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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,548	11/19/2003	Edward M. Sellers	62805.000040	5852
21967 7590 06/04/2007 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			EXAMINER JAGOE, DONNA A	
			ART UNIT 1614	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/715,548

Applicant(s)

SELLERS ET AL.

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,17,21,31-33,38-46 and 48-55 is/are pending in the application.
- 4a) Of the above claim(s) 6,17,21,31-33,38,49-51 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-46, 48, 52, 53 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/18/05 & 3/30/04.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant's election with traverse of the group VI invention, claims 39-46, 48, 52, 53 and 55 in the reply filed on December 18, 2006 is acknowledged. The traversal is on the ground(s) that the Examiner has not established that searching the different methods along with the composition claims would be an undue burden upon the Office.

This is not found persuasive because these inventions are distinct/unrelated for the reasons given in the restriction dated October 19, 2006 and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Moreover, because a search of each distinct/unrelated invention would not be coextensive with the other(s), and because each invention will require its own separate patentability analysis, an examination and search of multiple inventions in a single application would constitute a serious undue burden on the examiner.

Claims 6,17,21,31-33,38-46 and 48-55 are pending in this application. Claims 6, 17, 21, 31-34, 38, 49-51 and 54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 18, 2006.

Election of the specie methoxsalen and nicotine use disorders is further acknowledged.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the **product**, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. **Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.** Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of

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Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Claims 39-46, 48, 52, 53 and 55 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45, 46, 48 and 55 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following precedent is believed relevant to the instant case.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed.Cir.1997), *cert. denied*, 523 U.S. 1089, 118 S.Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." Eli Lilly, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed.Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics *when coupled with a known or disclosed correlation between function and structure*" Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d, 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed.Reg. at 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp.2d 216, 225 (W.D.N.Y. 2003).

Applying the reasoning of the above-cited case law to the facts at hand, the instant specification fails to provide an adequate written description of CYP2A6

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inhibitors having a lactone structure with a carbonyl moiety. The specification describes several agents having such a structure and activity, but does not detail the correlation between structure and function. It was known in the art at the time of the present invention that even compounds that share similar structural properties cannot be guaranteed to have the same level of activity (see the myriad of CYP2A6 inhibitors as in claim 46 wherein coumarin has activity as a blood-thinner, anti-fungicidal and anti-tumor activities and methoxsalen has activity as an agent for the treatment of psoriasis). Such is the unpredictable nature of the pharmaceutical arts, as acknowledged by Remington's Pharmaceutical Sciences (U), which states, "Two-dimensional structural organic formulas are very poor means of representing the physical, chemical or biologic properties of a molecule. Structural formulas merely depict the way the various atoms are strung together to form what is known as a *molecule*. Drugs that are strikingly similar in structure may demonstrate **widely differing pharmacologic properties**, while two drugs of apparently different structure can exhibit almost identical activity. Reference to Table I [see pages 421-424] easily confirms these facts. There are many factors other than simple structural variation that have an effect on the activity of a drug." (see first paragraph, column 1, page 425) Such factors include, but are not limited to, molecular size, shape, ionization, charge distribution, solubility, interatomic distance, geometric and stereochemical configurations, and the rigidity or flexibility of the molecule (see pages 425-426).

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No other detailed, relevant identifying characteristics are specified which would adequately describe other useful CYP2A6 inhibitors having a lactone structure with a carbonyl moiety.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44, 45, 46, 48 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation "two or more of said substances" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim because it is not disclosed what substances applicant intends. Did you mean two or more said CYP2A6 inhibitors? Clarification is required.

Claim 45 recites the limitation "a CYP2A6 inhibitor having a lactone structure with a carbonyl moiety" in lines 2-3 of the claim. Claim 46, dependent upon claim 45 recites several CYP2A6 inhibitors that do not have a "lactone structure with a carbonyl moiety", for example, hexamethylphosphoramide, imidazole antimycotics. Hence, there is insufficient antecedent basis for this limitation in the claim.

Regarding claim 46, line 9 of the claim drawn to "analogs thereof and derivatives thereof", a medicinal chemistry definition of analog is: An analog is a drug whose structure is related to that of another drug but whose chemical and biological properties

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may be quite different. The Examiner is unclear on the structure and or possible functions of an analog of any of the recited CYP2A6 inhibitors. The specification does not make it clear exactly what an analog might be. The Examiner suggests that the word analog be removed.

The term "related flavones" in claim 46 is a relative term, which renders the claim indefinite. The term "related flavones" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how "unrelated" a flavone can be, and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "unrelated flavone" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 39-46, 48, 52, 53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fernandez-Salguero et al. (V), Gonzalez et al. WO 95/34679 A2 and Draper et al. Arch Biochem Biophys (Y)

Fernandez-Salguero et al. teach CYP2A6 has the highest activity in the conversion of nicotine to cotinine (page 659, column 1, paragraph 3). Moreover, by using human liver microsomes, a correlation was found between coumarin 7-hydroxylation, CYP2A6 protein content and oxidation of nicotine to its iminium ion, the intermediate en route to cotinine. This may have considerable importance in nicotine metabolism, which could lead to differences in smoking habits (page 659 column 2, 1st full paragraph). It was discovered that in some populations the CYP2A6 allele was not found and in these populations, the metabolism of coumarin was undetectable (see page 655, esp. column 2).

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Gonzalez et al. teach CYP2A6 encodes a protein that metabolizes nicotine and coumarin and activates the tobacco-specific nitrosamine 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone) (NNK) (page 1, lines 26-30). Further, CYP2A6 has been associated with nicotine metabolism. Gonzalez et al. further disclose that nicotine, a component in tobacco, has several clinical uses, such as treatment of various neurological disorders such as Parkinson's disease and Alzheimer's disease. In addition, nicotine is used to treat tobacco addiction (page 11, lines 5-15).

Draper et al. teach that inhibitors of CYP2A6 include clotrimazole, diethyldithiocarbamate, ellipticine, ketoconazole, 8-methoxypsoralen (methoxsalen), 4-methylpyrazole, miconazole, and alpha naphthoflavone, (see abstract).

Both Fernandez-Salguero et al. and Gonzalez et al. teach the importance of CYP2A6 in the metabolism of nicotine, and recognize that the absence of CYP2A6 would inhibit the breakdown of nicotine its iminium ion, and then to cotinine. It would have been obvious to one of ordinary skill in the art to administer an agent that is a CYP2A6 inhibitor to regulate the metabolism of nicotine to cotinine, especially for the purpose of nicotine use disorders, as recognized by Fernandez-Salguero et al. who states that the regulation of nicotine metabolism may have considerable importance in nicotine metabolism, which could lead to differences in smoking habits (page 659 column 2, 1st full paragraph). Regarding the administration of two or more CYP2A6 inhibitors, it is recognized that coumarin regulates the metabolism of nicotine to cotinine. As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

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It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

Regarding claim 41, wherein the liver enzyme function is inhibited by greater than 80%, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. To quantify the level of inhibition of the liver enzyme function that was previously known to be inhibited by these agents as stated in the prior art is prima facie obvious.

Regarding claim 45, coumarin appears to be a "lactone structure with a carbonyl moiety". Regarding the slow release formulation, modes of administration are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to optimize them from the teachings of the prior art.

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Claims 39-45, 52, 53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berkman et al. (W) in view of Seaton et al. (X) and Draper et al. (Y).

Berkman et al. teach that CYP2A6 is the primary enzyme that transforms (S)-nicotine to (S) nicotine $\Delta^{1'5'}$ -iminium ion which is converted to (S) cotinine by the action of an exogenously added aldehyde oxidase (page 565, column 2, 2nd paragraph bridging to page 566, first paragraph). The formation of (S)-cotinine is strongly dependent on the previous drug administration history of each subject, and among the highest rates for (S)-cotinine formation at low concentration correlated well with immunoreactivity for cytochrome P450 2A6 (see abstract). The in vitro/in vivo correlation of the results suggests that the low amount of (S)-nicotine N-1'-oxygenation and the large amount of (S)-cotinine formed in human smokers are determined primarily by the kinetic properties of the human monooxygenase enzyme systems. It doesn't teach that the CYP2A6 enzyme enhanced inhibition of nicotine metabolism. It teaches that in the presence of CYP2A6, lots of (S)-cotinine was formed. Seaton et al. teach that there are many variables to the metabolism of nicotine in a human. It teaches that Phenobarbital, an inducer of CYP450 enzymes induces not only metabolism of nicotine to cotinine, but also metabolism of cotinine to secondary metabolites (page 472 2nd paragraph). Conversely cimetidine, an agent that inhibits the CYP450 enzymes (page 472, 4th paragraph) decreased rates of nicotine metabolism so that twice as much nicotine was excreted unchanged in urine of Macaques (page 473 1st paragraph). Regarding the method for treatment of a condition requiring the regulation of nicotine metabolism to cotinine wherein the condition is dependent on tobacco use, Seaton et al.

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teach that chronic ethanol administration produces inductive effects of the CYP450 enzymes and induction of nicotine metabolism after chronic ethanol administration resulted in decreased plasma nicotine concentrations (increased metabolism) and might explain the increased urge to smoke cigarettes sometimes associated with heavy alcohol consumption. It would have been made obvious to one of ordinary skill in art at the time it was made to inhibit the CYP2A6 enzyme to inhibit metabolism of nicotine since Berkman et al. teach that CYP2A6 is the primary enzyme that transforms (S)-nicotine to (S) nicotine $\Delta^{1'5'}$ -iminium ion which is converted to (S)-cotinine. It does not teach the specific agents that inhibit the CYP2A6 enzymes, however, Draper et al. teach that inhibitors of CYP2A6 include clotrimazole, diethyldithiocarbamate, ellipticine, ketoconazole, 8-methoxypsoralen (methoxsalen), 4-methylpyrazole, metyrapone, miconazole, alpha naphthoflavone, nicotine p-nitrophenol and tranylcypromine (see abstract). Seaton et al. teaches inhibitors of CYP450 decrease nicotine metabolism (chronic ethanol administration) and agents that induce CYP450 increase nicotine metabolism (Phenobarbital). Combined with the teaching of Berkman et al. that CYP2A6 is the primary enzyme that transforms (S)-nicotine to (S) nicotine $\Delta^{1'5'}$ -iminium ion which is converted to (S) cotinine one would have been motivated to employ inhibitors of CYP2A6 to inhibit nicotine metabolism. Regarding claim 41, wherein the liver enzyme function is inhibited by greater than 80%, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In

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such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. To quantify the level of inhibition of the liver enzyme function that was previously known to be inhibited by these agents as stated in the prior art is prima facie obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 39-46, 48, 52, 53 and 55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19, 27, 39-41 and 47-49 of copending Application No. 09/214851. Although the conflicting claims are not identical, they are not patentably distinct from each other because both cases are drawn to a method of regulating nicotine metabolism by a CYP2A6 inhibitor. The conflicting application further claims the addition of a CYP2B6 inhibitor, however, it appears that the CYP2B6 inhibitors overlap with the CYP2A6 inhibitors.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

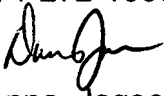
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Donna Jagoe
Patent Examiner
Art Unit 1614

May 17, 2007

 5/29/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER